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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,004	03/31/2004	Andrew T. Beckman	END5096.0515521	1279

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EXAMINER
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TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/815,004	BECKMAN ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/15/05, 3/31/04</u> .   | 6) <input type="checkbox"/> Other: ____                                     |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 6-7 are objected to because of the following informalities:

In regards to claims 6-7,

at line 1, the limitations "the introducer tube" should apparently read --an introducer tube--;

at line 2, the limitations "the introduction assembly" should apparently read --an introduction assembly-- to avoid a potential lack of antecedent basis.

Appropriate correction is required.

### ***Double Patenting***

2. Applicant is advised that should claims 6 and 9 be found allowable, claims 7 and 10, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1, 3 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Barsch (US Patent No. 6,234,177).

In regards to claim 1, Barsch disclose(s) a method of deployment of a biopsy marker at a biopsy surgical site within a body by use of a biopsy device, the method comprising:

retracting a cutter 52 to expose a cutter lumen 16 of a biopsy probe 10;

inserting a marker 42 and pusher 52 into the cutter lumen 16; and

distally advancing the cutter 52 to drive the pusher 52 and thus the marker 42 to cause deployment at the biopsy surgical site (see fig. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

*It is noted that the cutter and pusher, as claimed, do not appear to patentably distinguish from the pusher 52 of Barsch. Both elements (cutter and pusher) appear to constitute a single element that is detachably connected together and performs a single function (i.e. moving the marker for deployment); as such, both elements will be herein interpreted as single element numeral 52 of Basch.*

In regards to claim 3, Barsch disclose(s) a method further comprising:

assembling an introduction device 44 by inserting the marker 42 and pusher 52 into an introducer tube 44 sized for the cutter lumen 16 (see figs. 4C & 5-6).

In regards to claim 8, Barsch disclose(s) a method, further comprising proximally extending the pusher 52 from the cutter lumen 16 wherein distally advancing the cutter

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52 deploys the marker 42 as the cutter 52 approaches the cutter lumen 16 (see fig. 5; column 6/lines 58-66).

In regards to claims 9-10, Barsch disclose(s) a method, further comprising distally advancing the cutter 52 to position the pusher 52 across a distal lateral opening 22 in the biopsy probe 10 enabling retraction of the biopsy probe 10 without disturbing the deployed marker 42 (see column 7/lines 7-12).

In regards to claim 11, Barsch disclose(s) a method, further comprising percutaneously deploying the marker 42 during a core needle biopsy procedure (see column 6/lines 35-51).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Burbank et al. (US Patent No. 6,161,034).

Barsch discloses method as described above and further as follows:

In regards to claim 2, a method wherein a distal portion of the cutter lumen 16 communicates with a pneumatic source (see column 1/lines 20-45).

In regards to claims 6-7, Barsch disclose(s) a method, further comprising sizing a thickness of the introducer tube 44 to enable advancing the cutter 52 into the cutter lumen 16 with the introduction assembly inserted therein, wherein distally advancing the

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cutter 52 comprises distally advancing the cutter 52 into the cutter lumen 16 (see fig. 4C & 5-6; column 6/lines 35-51 & 58-66).

Barsch discloses a method, as described above, that teaches all the limitations of the claim including except Barsch does not teach the step of insufflating the biopsy surgical site with the pneumatic source. However, Burbank et al. disclose a method comprising the step of insufflating the biopsy surgical site (see column 14/lines 10-17 & 24-26).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch with a method step similar to that of Burbank et al. in order to accommodate fluid filled markers that are detectable by ultrasound or X-ray (see column 14/lines 24-26).

7. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Zarins et al. (US Patent No. 6,605,047).

Barsch discloses a method, as described above, that teaches all the limitations of the claim except Barsch does not teach the step of forming a pneumatic seal between the pusher and the introducer tube. However, Zarins et al. discloses a method comprising the step of forming a pneumatic seal 78 between the pusher 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 3I; column 9/line 65 to column 10/line 13; column 10/lines 18-21). It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a method similar to that of Barsch with a method step similar to that of Zarins et al. in order to deploy the marker out of the

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marker seat (see column 10/lines 9-13). Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Zarins et al. with a pressure-drawn pusher (i.e. plunger of a syringe) since such a modification would amount to a design choice.

8. Claims 12-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view Burbank et al. (US Patent No. 6,662,041).

In regards to claim 12, Barsch disclose(s) a device for deploying a biopsy marker 42 through a biopsy instrument having a probe 10 defining a cutter lumen 16 including a distal opening 22 and an accessible proximal opening and a cutter 52 translatable through the cutter lumen 16, the device comprising:

- a tube 44 configured to be received in the cutter lumen 16 and having a distal opening 48;

- a marker 42 slidably received in the tube 44; and

- a pusher 52 proximal to the marker 42 and slidably received in the tube 44, and having a proximal extension 70 configured for abutment with the cutter 52 to deploy the marker 42 through the lateral distal opening 48 (see figs. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to claim 13, Barsch disclose(s) a device, further comprising a proximal collar 82 attached proximally to the tube 44 and configured for manipulating the device into the cutter lumen 16 (see fig. 12).

In regards to claim 14, Barsch disclose(s) a device, further comprising an alignment feature (76, 78, 80) configured to rotationally orient the tube 44 in the cutter lumen 16 (see column 7/lines 36-42).

In regards to claim 15, Barsch disclose(s) a device, further comprising a pneumatic sealing feature (i.e. tight fitness of plunger 52 to the wall of the tube 44) dynamically sealing the pusher 52 to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to claim 19, Barsch disclose(s) a device, wherein at least a portion of the tube 44 and pusher 52 comprise a resilient material for flexibly inserting the device into the biopsy instrument 10 (see figs. 4C & 5-6).

Barsch discloses a device, as described above, that teaches all the limitations of the claim including a pusher that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface. However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Barsch with lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.



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9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Burbank et al. ('041) further in view of Lamoureux et al. (US Patent No. 6,554,760).

Barsch as modified by Burbank et al. discloses a device, as described above, that teaches all the limitations of the claim except Barsch as modified by Burbank et al. does not teach a removable sealing tip. However, Lamoureux et al. disclose a device comprising a removable sealing tip 32 engageable over the deployment opening (see fig. 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Barsch as modified by Burbank et al. with a seal similar to that of Lamoureux et al. in order to seal the biopsy needle and keep the marker from spilling out of the needle or body fluid from entering the needle prematurely (see Lamoureux et al., column 4/lines 22-24).

10. Claims 20-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Miller et al. (US Patent No. 6,638,235).

In regards to claim 20, Basch discloses a marker introduction device comprising:  
a tube 44 configured to be received in the cutter lumen 16 and having a lateral distal opening,

a marker 42 slidably received in the tube, and

a pusher 52 proximal to the marker 42 and slidably received in the tube 44, and having a proximal extension 70 configured for abutment with the cutter 52 to deploy the marker 42 through the lateral distal opening (see figs. 4C, 5-6, & 11-12; column 1/lines

20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to claim 21, Barsch disclose(s) a marker introduction device, wherein the pusher 52 is operably configured to dynamically seal to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to claim 24, Barsch disclose(s) a marker introduction device, wherein the pusher 52 is operably configured to close the distal opening 22 in the biopsy probe 10 subsequent to marker deployment (see column 7/lines 2-5).

Although Basch teaches the use of a biopsy system (see fig. 4B), Basch does not explicitly disclose the features of the biopsy probe. However, Miller et al. discloses a biopsy probe as follows:

In regards to claim 20, Miller et al. disclose(s) a core biopsy probe 10 including a cutter lumen (27, 34) that communicates between a distal opening 25 and an accessible proximal opening 100;

a biopsy handle 12 having an actuator 22 for cutting the biopsy sample through the biopsy probe 10 (see figs. 1-2; column 7/lines 4-6 & 21-23; column 8/lines 49-50 & 61-64; column 45-48).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Basch with a biopsy probe similar to that of Miller et al. in order to mark the biopsy site without retracting the biopsy probe and thus maintaining the percutaneous site (i.e. similar in function to an introducer sheath) (see Barsch, fig. 4B).

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11. Claims 22-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Miller et al. et al. ('235) further in view of Zarins et al. ('047).

Barsch as modified by Miller et al. et al. discloses a system, as described above, that teaches all the limitations of the claim except Barsch as modified by Miller et al. does not system with a pressure-drawn pusher that is capable of insufflating a surgical site. However, Zarins et al. discloses a system comprising a pneumatic seal 78 between the pusher 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 3I; column 9/line 65 to column 10/line 13; column 10/lines 18-21).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Miller et al. with an actuation system similar to that of Zarins et al. in order to deploy the marker out of the marker seat (see column 10/lines 9-13). Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Miller et al. as further modified by Zarins et al. with a pressure-drawn pusher (i.e. similar to a vacuum-actuated syringe plunger) that is capable of insufflating the surgical site since such a modification would amount to a design choice.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,056,700 to Burney et al. discloses a biopsy marker assembly and method of use.

US Patent No. 5,718,237 to Haaga discloses a biopsy needle.

US Patent No. 4,007,732 to Kvavle et al. discloses a method for location and removal of soft tissue.

US Patent No. 4,774,948 to Markham discloses a marking and retraction needle having a retractable needle.

US Patent No. 6,371,904 to Sirimanne et al. discloses a subcutaneous cavity marking device.

US Patent No. 6,375,634 to Carroll discloses an apparatus and method to encapsulate, kill and remove malignancies.

US Patent No. 6,602,204 to Dubrul et al. discloses an intraoperative tissue treatment method.

US Patent Application No. 2004/0030262 to Fisher et al. discloses a biodegradable polymer for marking tissue and sealing tracts.

US Patent No. 6,648,811 to Sierocuk et al. discloses a brachytherapy cartridge.

US Patent No. 4,900,304 to Fojioka et al. discloses a solid preparation administering instrument.


13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

  
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